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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,093	12/06/2004	Frank Seibertz	RO0953US(#90568)	1122

7590
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Baker Building
6th Floor
1940 East 6th Street
Cleveland, OH 44114

02/03/2010

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,093	Applicant(s) SEIBERTZ ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 24-41 and 47-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-23, 42-46 and 83-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments in the Request for Continued Examination, filed November 5, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 102 – Anticipation (Reinstated Rejection)

After further consideration of the claims, the previous 102 rejection as being anticipated by McGinity et al. has been reinstated in regard to the preparation claims. Applicant's arguments filed February 19, 2009 will be addressed following reinstated rejection.

Claims 1-6, 11-23 and 42-46 were rejected under 35 U.S.C. 102(b) as being anticipated by McGinity et al. (US 2001/0006677). The rejection stands withdrawn in

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regard to claims 1-5, 20-23. The rejection is reinstated in regard to claims 6, 11-19 and 42-46, and further applied to claims 87, 89 and 90.

The reference has been discussed in detail in the Office Action mailed November 14, 2008.

Applicant's Arguments

Applicant argues McGinity et al clearly fail to teach two or more gas forming components each being homogenously distributed within the preparation as set forth in present claim 6 because it discloses an "effervescent couple" comprising an acidic agent combined with an alkaline agent which is included in "effervescent granules. This argument is not persuasive.

Examiner's Response

The reference teaches an alkaline agent and an acid, which meets the limitation of at least two or more gas forming components. Further the granules may be in the state of a powder or fine particles to increase the dissolution rate (paragraph 0071). The granules are then placed into a mixer or hopper and mixed until thoroughly blended to form an effervescent mixture. The resulting films will have its components thoroughly dispersed throughout the film (paragraph 0094). This encompasses the components being homogeneously distributed within preparation. In regard to claims 87, 89 and 90, the binders include acacia, tragacanth, gelatin, starch, cellulose materials such as methyl cellulose and sodium carboxymethyl cellulose, alginic acids and salts thereof,

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polyethylene glycol, guar gum, polysaccharide, sugars, invert sugars, poloxamer, collagen, albumin, gelatin, cellulose in non-aqueous solvents, and combinations of the above and the like. Other binders include, for example, polypropylene glycol, polyoxyethylene-polypropylene copolymer, polyethylene ester, polyethylene sorbitan ester, polyethylene oxide or combinations thereof and the like (paragraph 0082), thus encompassing the instant claims.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 11-23, 42-46 and 83-90 stand rejected under 35 U.S.C. 103(a) as being unpatentable over McGinity et al. (US 2001/0006677) in view of Zerbe et al. (US 6,177,096). The rejection is maintained.

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Applicant's Arguments

Applicant argues that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider Block (believe Applicant means McGinity), et al. alone, or in combination with the cited secondary references, does not disclose each and every limitation of the present invention, nor would there be a reasonable expectation of success. It is respectfully submitted that the Examiner has applied an incorrect meaning to the terms "suspending agent" and "non-aqueous solvents" when interpreting the disclosure of the McGinity, et al. reference. Applicants submit that the Examiner's interpretation of a suspending agent is inappropriate. A mixture is not equivalent to a solution or a suspension. Contrary to the Examiner's opinion, the substances mentioned in paragraph [0082] would never be regarded as "non-aqueous solvents" by one skilled in the art. Furthermore, present claim 1 requires that the coating compound is dried (see the last process step). In a process by which a film is produced by coating a coating compound and subsequent drying, the drying process serves to remove the (liquid) solvents or dispersing agents that were used for preparing the coating compound. The Applicants thus submit that it would be quite apparent to one skilled in the art that the substances disclosed in paragraph [0082] of McGinity, et al. cannot be removed by drying. Applicants submit that since McGinity, et al. fail to disclose using a non-aqueous solvent in the process of making the compositions, the Examiner's conclusion (page 5, lines 8-10 of the Office action) stating that it would have been obvious to have dried the film to remove the

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solvent motivated by the desire to form a dry film is unfounded. The Applicants also submit that the Examiner's argument is inconsistent in consideration of the conclusion recited in the Office Action. Moreover, the Examiner has not indicated any reason why the effervescent components may be degraded by high temperatures. McGinity et al. do not teach that the effervescent components are susceptible to degradation by heat.

Examiner's Response

The Examiner disagrees and submits that polymers have been disclosed by the art as suspending agents. Young et al. (US 4,833,179) disclose suspending agents to form suspensions include polyvinyl alcohol, poly-N-vinyl pyrrolidone, polyacrylic acid, polyacrylamide and hydroxyalkyl cellulose. Thus the binding agents of McGinity et al. are considered "suspending agents" meeting the limitation of the instant claims. In regard to forming a solution or suspension, neither one of these terms appear to be recited in the instant claims and therefore the claims encompass mixtures, solutions and suspensions. Even if this was not the case, mixtures encompass solutions and suspensions because solutions and suspensions don't necessarily have components that react chemically. Further the claims do not recite or define suspending agents as non-aqueous solvents. The suspending agents are only required to be free from water. In regard to the drying step, McGinity et al. disclose using co-solvents and non-aqueous solvents with the polymer that may be used as the binders for the compositions.

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Examples of hot-melt extrudable effervescent granule binders include acacia, tragacanth, gelatin, starch, cellulose materials such as methyl cellulose and sodium carboxymethyl cellulose, alginic acids and salts thereof, polyethylene glycol, guar gum, polysaccharide, sugars, invert sugars, poloxamers (PLURONIC F68, PLURONIC F127), collagen, albumin, gelatin, cellulose in non-aqueous solvents, and combinations of the above and the like (paragraph 0082).

When using the non-aqueous solvents disclosed by McGinity et al. to form a film, it would be obvious to remove these solvents in order to form a film. This is supported by the secondary reference. Additionally McGinity et al. disclose that certain hot melt procedures degrade the actives. In KSR v. Teleflex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try" such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to make films using a method that does not degrade the extruded materials. Accordingly, it would have been obvious to one of ordinary skill in the art to look to other methods in order to avoid this. Therefore it would have been obvious to use the methods of Zerbe et al. to make the films of McGinity et al., especially when non-aqueous solvents are used. Thus it is believed that McGinity et al. teaches non-aqueous solvents and McGinity itself further supports why one of ordinary skill in the art would want to explore other methods of forming the films.

In regard to McGinity et al. not teaching that the effervescent components are susceptible to degradation by heat, McGinity et al. disclose "Hot-melt extrusion

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processes in the art have generally required extremely elevated temperatures (>150.degree. C.). These temperatures could degrade extruded materials such as those that combine to form an effervescent composition" (paragraph 0015).

Claims 1-6, 11-23, 42-46 and 83-90 are rejected.

Claims 7-10, 24-41 and 47-82 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612